**Policies and Procedures for Protecting Human Research Participants in CDC-Funded Research**

## General

All funded research (whether through grants, cooperative agreements, contracts, or purchase orders) must comply with the Federal regulations for protecting human participants found in Title 45 Code of Federal Regulations (CFR) Part 46. The Procurement and Grants Office (PGO) will ensure that all external collaborating sites in a research study have assurances and institutional review board (IRB) approval for the proposed research **before** the research is initiated. PGO has the option of either holding the award or making the award and restricting funds from expenditure on human participants until all Federal requirements are met as specified in 45 CFR 46. PGO will make this determination on a case by case basis.

It is the responsibility of the CIO Human Subjects Contact (HSC)* to inform PGO whether a proposed study is research that involves human participants, whether CDC staff are participating in the research as co-investigators, and if any exemptions are claimed. It is also the Human Subjects Contact's responsibility for ensuring that CDC IRB approval is determined where CDC staff are participating in the research.

## Grants/Cooperative Agreements

For those programs involving research where humans are expected to be participants, the HSC must make certain the following language is included in the Human Subjects subpart of the Other Requirements section in the program announcement:

> "If the proposed project involves research on human participants, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR 46) regarding the protection of human research participants. Assurance must be provided to demonstrate that the project will be subject to initial and continuing reviews by an appropriate institutional review board. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and forms provided in the application kit."

If CDC scientists will be co-investigators in the research project, the HSC must make certain the following insert related to obtaining CDC IRB approval is included under the CDC Activities listed under the Program Requirements section in the program announcement:

"Assist in the [e.g., design of the study, design of the instruments, development of methods and procedures for the study, collection of the data, analysis of the data, interpretation of the data, or co-authorship of the paper] for IRB review by all institutions participating in the research project.

The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed."

To verify that the HSC has reviewed the program announcement and included all appropriate language in the announcement if humans are expected to be participants in the research, the HSC must sign the certification of available funds document (CDC 0.1067 form) which must be submitted to GMB, PGO when the final version of the program announcement is submitted.

When CIOs submit funding memoranda for new and continuation awards, they must attach to the memorandum, the "Tracking Form for Research Funded Through CDC Grants and Cooperative Agreements" which indicates whether humans will be participating as subjects in the proposed research award. The form will also identify if CDC scientists will be co-investigators; and if so, whether the CDC IRB has reviewed and approved the protocol. The form is to be signed and dated by the HSC. If an exemption is claimed under 46.101, GMB, PGO will promptly forward the tracking form to the Deputy Associate Director for Science for concurrence.

For all research awards involving humans as participants, GMB, PGO will enter one or more of the following codes into the award module of the Grants Management Information System (GMIS):

30 - human subjects - one site
33 - human subjects - multiple sites
36 - human subjects - multiple sites including CDC as one of the sites

40 - awardee missing an assurance or certification
43 - any of the participating sites missing assurances or certifications
46 - certification missing for CDC

**Contracts/Purchase Orders**

When research is developed in the first phase and conducted in the second phase of a contract:

At the time the RFC is submitted to PGO, the CIO HSC** informs PGO that the study is research involving humans as participants, indicates whether CDC investigators are involved, and whether an exemption is claimed. Funds are not restricted for phase one. Phase two cannot begin (i.e. funds are restricted or approval to proceed to phase two is withheld) until all assurances and IRB approvals are obtained. If CDC investigators are

participating in the research, the CIO HSC must inform PGO of CDC IRB approval before approval is given to the contractor to proceed with phase two.

When the research protocol is described in the RFC:

CIO HSC** informs PGO that the study is research involving humans as participants, whether CDC investigators are participating in the research, and if an exemption is claimed. If CDC investigators are participating, the CDC IRB must approve the research before the award is made. The CIO HSC informs PGO that research is approved by CDC IRB.

**The HSC completes, signs and dates the "Clearance Checksheet for Contracts" form and submits it with the RFC.

In addition to the standard language pertaining to research involving human participants, the Request for Proposal (RFP) will contain the following language when CDC scientists are to be involved as co-investigators in the contract:

"CDC's Institutional Review Board (IRB)

It is anticipated that this requirement will involve participation by CDC investigators in the research activities. Therefore, the CDC IRB must approve the research protocol prior to contract award. If the CDC IRB approval is not received prior to contract award then a restricted award can be made. Contract awards issued on a restricted basis will prohibit the use of any funds that are associated with the use of human subjects."

In addition to the standard language pertaining to research involving human participants, the contract will contain the following language when CDC investigators are to be involved as investigators and the CDC IRB has not met prior to award:

"Notice of Restricted Award Pending CDC Institutional Review Board (IRB) Approval

It has been determined that this requirement will involve participation by CDC investigators in the research activities; therefore, the CDC IRB is required to approve the protocol prior to beginning any tasks or using Federal funds that involve human subjects. Once the CDC IRB approval of the protocol is rendered, the Contracting Officer will provide written notification removing the award restriction."

**Grants/Cooperative Agreements/Contracts**

PGO will promptly send all research tracking forms and clearance checksheets that identify exempted research to the Deputy Associate Director for Science for concurrence.

**Special Notes**:

All determinations that research is exempt from IRB review, whether for a grant, a cooperative agreement, a contract, or a purchase order must be reviewed and approved by the Deputy Associate Director for Science. This includes determinations made by CIO HSCs, by awardee IRBs, or by other participating organization IRBs. The research tracking form or checksheet must be completed, signed, and dated by the HSC. Upon receipt, PGO will promptly send the tracking form or checksheet to the Deputy Associate Director for Science for concurrence.

If a CIO does not provide all the required human subjects information to PGO, PGO will assume that any proposed activity involving data collection is research and CDC investigators are participating in the study and the project is therefore subject to the human subjects regulations.

Disagreements between a CIO HSC and PGO involving whether research is subject to the human subjects regulations or whether the project is exempt from IRB review, etc. will be resolved by the Deputy Associate Director for Science who should be contacted immediately by either party by e-mail, telephone, or memorandum with notification to the other party.

*A Human Subjects Contact is a person designated by the CIO to serve as the liaison with the human subjects office at CDC. The Human Subjects Contact is generally the Associate Director for Science or a specific designee. A list of human subjects contacts is maintained by the Deputy Associate Director for Science and is located on the Associate Director for Science Intranet homepage.

Attachments:

Tracking Form for Research Funded Through CDC Grants and Cooperative Agreements
Clearance Checksheet for Contracts
CDC form 0.1067
Format for Memorandum to OPRR for Single Project Assurance